

REMARKS

Claims 53-60 are presently pending in the case. Claim 55 has been amended to correct a clerical error.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under 35 USC 102

The Examiner rejected claims 53-55, 57 and 59 under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,727,546 to Clarke et al (hereinafter Clarke et al). The rejection is traversed.

Clarke et al does not anticipate claims 53-55, 57 and 59. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Clarke et al fails as an anticipatory reference.

Independent claim 53 is not anticipated by Clarke et al. Claim 53 is to a method for aerosolizing a pharmaceutical formulation, the method comprising, inter alia, providing a valve to prevent respiratory gases from flowing to the lungs when a user attempts to inhale, and then abruptly permitting respiratory gases to flow to the lungs by opening the valve when a threshold actuating vacuum caused by the attempted inhalation is exceeded, and providing a flow regulator within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases. Clarke et al does not provide both a threshold valve as claimed and a flow regulator as claimed. It is respectfully submitted that these positively recited features are absent in the disclosure of Clarke et al, thereby precluding a section 102 rejection because each and every element of the claim is not taught by the cited reference.

The Examiner directs the Applicant's attention to the embodiment of Clarke et al. shown in Figures 2(a)-2(c). However, this embodiment of Clarke et al discloses a single valve 27 and does not disclose a separate threshold valve and flow regulator. Since all elements of claim 53 are not accounted for in Clarke et al, Clarke et al does not anticipate claim 53. Furthermore, the valve 27 of Clarke et al also does not meet the limitations of the Applicant's flow regulator. According to claim 53, the flow resistance through the flow regulator is low when the respiratory gases are permitted to flow and increases when the vacuum generated by the user increases. The Clarke et al device does not operate in this manner. Before respiratory gases are permitted to flow, the Clarke et al valve is in the position shown in Figure 2(a). As respiratory gases are permitted to flow, the valve (27) of Clarke et al rotates counterclockwise from the position shown in Figure 2(a). In going from the position shown in Clarke et al's Figure 2(a) to the position shown in Figure 2(b), the flow resistance decreases, i.e. the opening caused by the movement of element 27 increases. Thus, the flow resistance is not low when gases are permitted to flow and then increases, as required by claim 53. Instead, the flow resistance of Clarke et al is high when respiratory gases begin to flow and then decreases up until the position shown in Figure 2(b).

The Examiner's comments concerning the Figure 2(a)- 2(c) embodiment in the Office Action of September 11, 2008 do not serve to advance the Examiner's position. The Examiner points out that the flow resistance of Clarke et al increases in going from the position of Figure 2(b) to the position of Figure 2(c). However, the Examiner's point is immaterial to the issue at hand. The claim 53 recitation at issue relates to when the respiratory gases are **first** permitted to flow. The Examiner, on the other hand, improperly chooses a starting point that occurs after the respiratory gases have been flowing. The Examiner ignores the decreasing flow resistance in Clarke et al when going from the position of Figure 2(a) to the position of Figure 2(b). Applicant respectfully requests that the Examiner consider all the claim language in claim 53.

Applicant requests withdrawal of the rejection of claim 53 under 35 U.S.C.

§102(b). In addition, Applicant requests withdrawal of the rejection of claims 54, 55, 57 and 59 which depend from claim 53 and are not anticipated by Clarke et al for at least the same reasons as claim 53.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 58 and 60 under 35 USC 103(a) as being unpatentable over Clarke et al. The rejection is traversed.

Clarke et al does not render claims 58 and 60 unpatentable. Claims 58 and 60 depend from claim 53 which is not rendered unpatentable by Clarke et al for the reasons given above. Since claims 58 and 60 depend from an allowable claim, they too are allowable. In addition, claim 58 is allowable over Clarke et al in that Clarke et al fails to disclose or teach the duckbill valve recited in the claim. Claim 60 is also not rendered unpatentable by Clarke et al in that claim 60 recites a parallel flow arrangement that is not disclosed or taught by Clarke et al.

The Examiner rejected claim 56 under 35 USC 103(a) as being unpatentable over Clarke et al in view of U.S. Patent No. 6,116,237 to Schultz et al (hereinafter Schultz et al). The rejection is traversed.

Claim 56 depends from allowable claim 53. Schultz et al is not relied upon to make up for the deficiencies of Clarke et al, nor does it. Since Schultz et al does not make up for these deficiencies, the combination of Clarke et al and Schultz et al also fails to render claim 53 unpatentable. Claim 56 depends from claim 53 and is also allowable over the combination of references.

Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: December 10, 2008

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